

TRANSCATHETER MITRAL REPAIR WITH A SUTURELESS NEOCHORDAL DEVICE: PRECLINICAL EXPERIENCE

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OBJECTIVE: An animal study was performed to evaluate technical feasibility and performance of a transcatheter mitral neochordae repair system.

METHODS: Five adult swines and five adult sheep underwent left thoracotomy through the third intercostal space. A novel catheter based sutureless chordal replacement implant (Chordart, Coremedic, Biel, Switzerland) was introduced either transcatheter through a 14F sheath in the swine model or open beating heart with CPB support on the sheep model. The posterior mitral leaflet was grasped at the P2 segment, and it was punctured. The implant was delivered to the posterior papillary muscle using echocardiographic, fluoroscopic or visual guidance, on the beating heart. Subsequently the leaflet component was deployed using a flexible delivery system to the central section of the posterior leaflet. Finally, the transcatheter delivery was withdrawn from the working sheath and the atrial purse-string closed. The 5 swines were sacrificed acutely, while the sheep were sacrificed at 180 days.

RESULTS: All animal survived the acute implant. The sutureless chordal replacement implant was successfully implanted in all animals, without side effect noted to the mitral valve and substructure. At necropsy, location of the implant was within a few millimeters of the leaflet free boundary (2.5 ± 3 mm). No leaflet lesion was observed. In 3 animals, papillary muscle fixation element was implanted more than 5mm from the muscle tip but within the targeted

papillary muscle. In the 5 long term survivors, the implanted device showed satisfactory healing, no inflammatory or toxicity response, and no chordae dehiscence.

CONCLUSIONS: Transcatheter minimally-invasive, beating-heart implantation of a sutureless neochordae implant is feasible. This approach may be an alternative to open surgical procedures in high risk degenerative MR patients or even in young patients who want to avoid an operation.